

Food and Drug Administration, HHS

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distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5560 Temperature regulated water mattress.

(a) *Identification*. A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

§ 880.5570 Hypodermic single lumen needle.

(a) *Identification*. A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

(b) *Classification*. Class II (performance standards).

§ 880.5580 Acupuncture needle.

(a) *Identification*. An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification*. Class II (special controls). Acupuncture needles must

comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

§ 880.5630 Nipple shield.

(a) *Identification*. A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 33804, July 25, 2001]

§ 880.5640 Lamb feeding nipple.

(a) *Identification*. A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.5680 Pediatric position holder.

(a) *Identification*. A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an

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intravascular injection is administered.

(b) *Classification*. Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 46952, Sept. 10, 2001]

§ 880.5700 Neonatal phototherapy unit.

(a) *Identification*. A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.

(b) *Classification*. Class II (performance standards).

§ 880.5725 Infusion pump.

(a) *Identification*. An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

(b) *Classification*. Class II (performance standards).

§ 880.5740 Suction snakebite kit.

(a) *Identification*. A suction snakebite kit is a device consisting of a knife, suction device, and tourniquet used for first-aid treatment of snakebites by removing venom from the wound.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

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subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 38805, July 25, 2001]

§ 880.5760 Chemical cold pack snakebite kit.

(a) *Identification*. A chemical cold pack snakebite kit is a device consisting of a chemical cold pack and tourniquet used for first-aid treatment of snakebites.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a chemical cold pack snakebite kit that was in commercial distribution before May 28, 1976. Any other chemical cold pack snakebite kit shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 69682, Oct. 21, 1980, as amended at 52 FR 17739, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 880.5780 Medical support stocking.

(a) *Medical support stocking to prevent the pooling of blood in the legs—(1) Identification*. A medical support stocking to prevent the pooling of blood in the legs is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for use in the prevention of pooling of blood in the leg.

(2) *Classification*. Class II (performance standards).

(b) *Medical support stocking for general medical purposes—(1) Identification*. A medical support stocking for general medical purposes is a device that is constructed of elastic material and designed to apply controlled pressure to the leg and that is intended for medical purposes other than the prevention of pooling of blood in the leg.